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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/015,869	12/11/2001	Kevin P. Baker	GNE.2830P1C45	9681

35489 7590 12/14/2004

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EXAMINER

HAMUD, FOZIA M

ART UNIT	PAPER NUMBER
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1647

DATE MAILED: 12/14/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/015,869

Applicant(s)

BAKER ET AL.

Examiner

Fozia M Hamud

Art Unit

1647

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 September 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 33-36, 38-40 and 44-54 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 33-36 and 44-54 is/are rejected.
- 7) ☒ Claim(s) 38-40 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 12/11/01 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 09/09/04.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

1a. Receipt of Applicant's arguments and amendment, filed on 09 September 2004, is acknowledged. Claims 1-32, 37 and 41-43 have been cancelled and new claims 48-54 have been added. Thus claims 33-36, 38-40, 44-54 are pending and under consideration.

1b. Applicants are thanked for providing copies of the references cited on the on the PTO-1449 form submitted by Applicants on 09 September 2004.

Response to Applicants' arguments:

2. The following previous objection is withdrawn in light of Applicants amendments filed on 09/09/04:

2a. All the rejections made against canceled claims 28-32, 37 and 41-43 are moot.

3. Priority:

3a. Applicants submit that the claimed subject matter relies on the gene amplification assay (Example 143 of the instant specification) for patentable utility which was first disclosed in U.S. Provision Application No. 60/162,506, filed October 29, 1999, priority to which has been claimed in this application. Example 20, disclosed in the Provisional Application No. 60/162,506, provides the support required to establish utility for the nucleic acid encoding the PRO1293 polypeptide and the nucleic acid of SEQ ID NO:76. Accordingly, Applicants submit that the subject matter of the instant claims is supported by the disclosure in Provisional Application No. 60/162,506. Therefore, the effective filing date of

this application is October 29, 1999, the filing date of Provisional Application No. 60/162,506.

This argument has been considered and is found persuasive in part. The gene amplification assay in U.S. Provisional Application No. 60/162,506, filed October 29, 1999, provides a specific and substantial asserted utility for the isolated nucleic acid of SEQ ID NO:76, because the assay shows approximately 2 fold amplification of DNA sequences in lung and colon tumors compared to normal controls, thus providing a specific and substantial asserted utility for the nucleic acid of SEQ ID NO:76. However, neither the isolated nucleic acid encoding the polypeptide of SEQ ID NO:77, nor variants of the nucleic acid of SEQ ID NO:76, are supported by the disclosure in U.S. Provision Application No. 60/162,506, filed October 29, 1999, because this prior application does not show that "all possible" nucleic acids encoding the polypeptide of SEQ ID NO:77 or variants of the nucleic acid of SEQ ID NO:76 are also amplified in these tumors.

Accordingly, only claims drawn to the full length of the nucleic acid of SEQ ID NO:76 (claims 33, 38-40, 47) are afforded the filing date of 29 October 1999.

Therefore, claims 34-36 and 48-54 which are drawn to an isolated nucleic acid encoding the polypeptide of SEQ ID NO:77, and nucleic acids that hybridize the nucleic acid of SEQ ID NO:76, respectively, are not afforded the benefit of the filing date of the U.S. Provisional Application No. 60/162,506, which was filed October 29, 1999. Thus, claims 34-36 and 48-54 are afforded an effective filing date of 12/11/2001, which is the filing date of the current application.

Claim Rejections - 35 U.S.C. § 112:

Art Unit: 1647

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4a. Claims 33-36, 44-47 stand rejected and new claims 48-54 are rejected under 35 U.S.C. 112, first paragraph, for reasons of record, set forth in the office action mailed on 06/14/04, pages 4-8, and reiterated here, because the instant specification does not reasonably provide enablement for an isolated nucleic acid encoding the polypeptide of SEQ ID NO:77 or variants of the nucleic acid of SEQ ID NO:76. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. Applicants submit the following arguments regarding this rejection.

Applicants submit that the cancellation of Claims 28-32, 37 and 41-43 renders the rejection of these claims moot. Applicants also submit that amended claim 33, no longer recites a nucleotide acid sequence encoding the polypeptide of SEQ ID NO: 77. Applicants argue that based on the instant disclosure, which details how to make and use the claimed nucleic acids and the advanced knowledge in the art at the time of filing, one skilled in the art would know exactly how to make and use the claimed nucleic acids for the diagnosis of lung and colon cancer; for example, by using diagnostic methods based on hybridization to such amplified Sequences.

These arguments have been considered, but are not deemed persuasive.

Amended claims 34-36 are drawn to an isolated nucleic acid encoding the polypeptide of SEQ ID NO:77, however, as was previously discussed (see paragraph 3a of this office action), the instant application is non-enabling for an isolated nucleic acid encoding the polypeptide of SEQ ID NO:7. Regarding claims 48-54, the instant specification is non enabling for the variants recited in these claims. The specification does not demonstrate that nucleic acids that are at least 20, 50, 60, 80, 90 or 100 nucleotides in length that hybridize to the nucleic acid of SEQ ID NO:76 or complement thereof, are amplified in primary lung tumors and in primary colon tumors compared to DNA isolated from normal controls, and would therefore, be useful in diagnosing said diseases.

Regarding claim 33, the specification does not disclose the structure of the extracellular domain coding region within the nucleic acid that encodes the of SEQ ID NO:76. Therefore, one skilled in the art would be able to visualize said structure.

Claim Rejections - 35 U.S.C. § 102:

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

5a. Claims 34-36 stand rejected and new claims 48-54 are rejected under 35 U.S.C § 102 (a) as being anticipated by Baker et al (WO200012708; published on 09 March 2000).

Applicants submit that the subject matter of the instant claims is supported by the disclosure in Provisional Application No. 60/162,506. Therefore, the effective filing date of this application is October 29, 1999, the filing date of Provisional Application No. 60/162,506.

This argument is not found persuasive, because the invention of instant. The subject matter of claims 34-36 and 48-54 is not entitled to the October 29, 1999 filing date, but are entitled the effective filing date of the current application which is 12/11/2001, because the parent application does not a specific and substantial asserted utility or a well established utility for the subject of claims 34-36 and 48-54, (see paragraph 3a of this office action).

New Rejections:

Claim Rejections - 35 U.S.C. §101:

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

6a. Claims 46-47 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. Claims 46-47 recite " a host cell comprising...", which encompasses the host cell, as it occurs in nature, for example, as a gene therapy patient. However, since Applicants do not intend to claim a naturally occurring products amendment of the claims to show the hand

of man would obviate this rejection. It is suggested that claim 46 be amended to recite "an isolated host cell.....". Appropriate correction is required.

Claim Rejections - 35 U.S.C. § 102:

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7a. Claims 48-54 are rejected under U.S.C. § 102 (a) as being anticipated by Robert Strausberg (10/20/200), OR Ansorge et al (02/18/2000).

Strausberg discloses an isolated nucleic acid molecule that comprises at least 735 contiguous nucleotides of the nucleic acid of SEQ ID NO:76 of the instant application. (See attached copies of the comparison of SEQ ID NO:76 of the instant invention and the sequence of the references (SEQUENCE COMPARISON 'A').

Instant claims 48-54 are drawn to an isolated nucleic acid that is at least 20 to 100 nucleotides in length that hybridize to the nucleic acid of SEQ ID NO:76. Therefore, since the Straubserg reference comprises at least 735 nucleotides of SEQ ID NO:76, it would be expected to hybridize to the complement of the nucleic acid of SEQ ID NO:76, and the complement of the Straubserg nucleic acid would be expected to hybridize to the nucleic acid of SEQ ID NO:76. Thus, the Straubserg reference anticipates instant claims 48-54 in the absence of any evidence to the contrary.

Art Unit: 1647

7b. Claims 48-54 are rejected under U.S.C. § 102 (a) as being anticipated by Ansorge et al (02/18/2000).

Ansorge et al disclose an isolated nucleic acid molecule that comprises at least 1153 contiguous nucleotides of the nucleic acid of SEQ ID NO:76 of the instant application. (See attached copies of the comparison of SEQ ID NO:76 of the instant invention and the sequence of the references (SEQUENCE COMPARISON 'B').

Instant claims 48-54 are drawn to an isolated nucleic acid that is at least 20 to 100 nucleotides in length that hybridize to the nucleic acid of SEQ ID NO:76. Therefore, since the Ansorge et al reference comprises at least 1153 nucleotides of SEQ ID NO:76, it would be expected to hybridize to the complement of the nucleic acid of SEQ ID NO:76, and the complement of the Ansorge et al nucleic acid would be expected to hybridize to the nucleic acid of SEQ ID NO:76. Thus, the Ansorge et al reference anticipates instant claims 48-54 in the absence of any evidence to the contrary.

Claim Objections:

8. Claims 38-40 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion:

9. No claim is allowed.

Advisory Information:


Art Unit: 1647

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Fozia M Hamud whose telephone number is (571) 272-0884. The examiner can normally be reached on Monday, Thursday-Friday, 6:00 am to 4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda G Brumback can be reached on (571) 272-0961. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Fozia Hamud
Patent Examiner
Art Unit 1647
07 December 2004


JANET ANDRES
PRIMARY EXAMINER

A

RESULT 14

HSM800499

LOCUS HSM800499 1182 bp mRNA linear PRI 18-FEB-2000

DEFINITION Homo sapiens mRNA; cDNA DKFZp586E2023 (from clone DKFZp586E2023).

ACCESSION AL050202

VERSION AL050202.1 GI:4884441

KEYWORDS

SOURCE Homo sapiens (human)

ORGANISM Homo sapiens

Eukaryota; Metazoa; Chordata; Craniata; Vertebrata; Euteleostomi;
Mammalia; Eutheria; Primates; Catarrhini; Hominidae; Homo.

REFERENCE 1 (bases 1 to 1182)

AUTHORS Ansorge,W., Wirkner,U., Mewes,H.W., Gassenhuber,J. and Wiemann,S.

TITLE Direct Submission

JOURNAL Submitted (15-MAY-1999) MIPS, Am Klopferspitz 18a, D-82152
Martinsried, GERMANY

COMMENT Clone from S. Wiemann, Molecular Genome Analysis, German Cancer
Research Center (DKFZ); Email s.wiemann@dkfz-heidelberg.de;
sequenced by EMBL (European Molecular Biology Laboratories,
Heidelberg/Germany) within the cDNA sequencing consortium of the
German Genome Project.
This clone (DKFZp586E2023) is available at the RZPD in Berlin.
Please contact the RZPD: Ressourcenzentrum, Heubnerweg 6, 14059
Berlin-Charlottenburg, GERMANY; Email: clone@rzpd.de Further
information about the clone and the sequencing project is available
at <http://www.mips.biochem.mpg.de/proj/cDNA/>.

FEATURES

source

Location/Qualifiers

1..1182

/organism="Homo sapiens"

/mol_type="mRNA"

/db_xref="RZPD:DKFZp586E2023"

/db_xref="taxon:9606"

/clone="DKFZp586E2023"

/tissue_type="uterus"

/clone_lib="586 (synonym: hutel). Vector pSport1; host

DH10B;_sites.NotI+_SalI/MluI"

/dev_stage="adult"

polyA_signal

1145..1150

polyA_site

1169

ORIGIN

Query Match 57.9%; Score 1151.4; DB 9; Length 1182;
Best Local Similarity 99.9%; Pred. No. 4.8e-155;
Matches 1152; Conservative 0; Mismatches 1; Indels 0; Gaps 0;

Qy	837	AGGCTACGAATACTCGGACCAGAAGTCGGGAAAGTCAAAGGGGAAGGATGTAACTTGGC	896
Db	30	AGGCTACGAATACTCGGACCAGAAGTCGGGAAAGTCAAAGGGGAAGGATGTAACTTGGC	89
Qy	897	GGAGTTCGCTGTGGCTGCAGGGGACCAGATGCTTTACAGGAGTGAGGACATCCAGCTAGA	956
Db	90	GGAGTTCGCTGTGGCTGCAGGGGACCAGATGCTTTACAGGAGTGAGGACATCCAGCTAGA	149
Qy	957	TTACAAAAACAACATCCTGAAGGAGAGGGCGGAGCTGGCCACAGCCCCCTGCCTGCCAA	1016
Db	150	TTACAAAAACAACATCCTGAAGGAGAGGGCGGAGCTGGCCACAGCCCCCTGCCTGCCAA	209

Sequence Comparison
'g'



Sequence Comparison

Qy	1017	GTACATCGACCTAGACAAAGGGTTCCGGAAGGAGAACTGCAAATAGGGAGGCCCTGGGCT	1076
Db	210	GTACATCGACCTAGACAAAGGGTTCCGGAAGGAGAACTGCAAATAGGGAGGCCCTGGGCT	269
Qy	1077	CCTGGGCTGGGCCAGCAGCTGCACCTCTCCTGTCTGTGCTCCTCGGGGCATCTCCTGATGC	1136
Db	270	CCTGGGCTGGGCCAGCAGCTGCACCTCTCCTGTCTGTGCTCCTCGGGGCATCTCCTGATGC	329
Qy	1137	TCCGGGGCTCACCCCCCTTCCAGCGGCTGGTCCCGCTTTCCTGGAATTTGGCCTGGGCGT	1196
Db	330	TCCGGGGCTCACCCCCCTTCCAGCGGCTGGTCCCGCTTTCCTGGAATTTGGCCTGGGCGT	389
Qy	1197	ATGCAGAGGCCGCCTCCACACCCCTCCCCAGGGGCTTGGTGGCAGCATAGCCCCACCC	1256
Db	390	ATGCAGAGGCCGCCTCCACACCCCTCCCCAGGGGCTTGGTGGCAGCATAGCCCCACCC	449
Qy	1257	CTGCGGCCTTTGCTCACGGGTGGCCCTGCCCACCCCTGGCACAACCAAAATCCCACTGAT	1316
Db	450	CTGCGGCCTTTGCTCACGGGTGGCCCTGCCCACCCCTGGCACAACCAAAATCCCACTGAT	509
Qy	1317	GCCCATCATGCCCTCAGACCCCTTCTGGGCTCTGCCCGCTGGGGGCCTGAAGACATTCTTG	1376
Db	510	GCCCATCATGCCCTCAGACCCCTTCTGGGCTCTGCCCGCTGGGGGCCTGAAGACATTCTTG	569
Qy	1377	GAGGACACTCCCATCAGAACCTGGCAGCCCCAAAACCTGGGGTCAGCCTCAGGGCAGGAGT	1436
Db	570	GAGGACACTCCCATCAGAACCTGGCAGCCCCAAAACCTGGGGTCAGCCTCAGGGCAGGAGT	629
Qy	1437	CCCACTCCTCCAGGGCTCTGCTCGTCCGGGGCTGGGAGATGTTCTGGAGGAGGACACTC	1496
Db	630	CCCACTCCTCCAGGGCTCTGCTCGTCCGGGGCTGGGAGATGTTCTGGAGGAGGACACTC	689
Qy	1497	CCATCAGAACTTGGCAGCCTTGAAGTTGGGGTCAGCCTCGGCAGGAGTCCCACTCCTCCT	1556
Db	690	CCATCAGAACTTGGCAGCCTTGAAGTTGGGGTCAGCCTCGGCAGGAGTCCCACTCCTCCT	749
Qy	1557	GGGGTGCTGCCTGCCACCAAGAGCTCCCCACCTGTACCACCATGTGGGACTCCAGGCAC	1616
Db	750	GGGGTGCTGCCTGCCACCAAGAGCTCCCCACCTGTACCACCATGTGGGACTCCAGGCAC	809
Qy	1617	CATCTGTTCTCCCCAGGGACCTGCTGACTTGAATGCCAGCCCTTGCTCCTCTGTGTTGCT	1676
Db	810	CATCTGTTCTCCCCAGGGACCTGCTGACTTGAATGCCAGCCCTTGCTCCTCTGTGTTGCT	869
Qy	1677	TTGGGCCACCTGGGGCTGCACCCCTGCCCTTTCTCTGCCCCATCCCTACCCTAGCCTTG	1736
Db	870	TTGGGCCACCTGGGGCTGCACCCCTGCCCTTTCTCTGCCCCATCCCTACCCTAGCCTTG	929
Qy	1737	CTCTCAGCCACCTTGATAGTCACTGGGCTCCCTGTGACTTCTGACCCTGACACCCCTCCC	1796
Db	930	CTCTCAGCCACCTTGATAGTCACTGGGCTCCCTGTGACTTCTGACCCTGACACCCCTCCC	989
Qy	1797	TTGGACTCTGCCTGGGCTGGAGTCTAGGGCTGGGGCTACATTTGGCTTCTGTACTGGCTG	1856
Db	990	TTGGACTCTGCCTGGGCTGGAGTCTAGGGCTGGGGCTACATTTGGCTTCTGTACTGGCTG	1049
Qy	1857	AGGACAGGGGAGGGAGTGAAGTTGGTTTGGGGTGGCCTGTGTTGCCACTCTCAGCACCCC	1916



Sequence Comparison

'B'

Db	1050		AGGACAGGGGAGGGAGTGAAGTTGGTTTGGGGTGGCCTGTGTTGCCACTCTCAGCACCCC	1109
Qy	1917		ACATTTGCATCTGCTGGTGGACCTGCCACCATCACAATAAAGTCCCCATCTGATTTTTTAA	1976
Db	1110		ACATTTGCATCTGCTGGTGGACCTGCCACCATCACAATAAAGTCCCCATCTGATTTTTTAG	1169
Qy	1977	AAAAAAAAAAAA		1989
Db	1170	AAAAAAAAAAAA		1182

